

Application No. 09/431,469  
Amendment dated March 7, 2005  
Reply to Final Office Action of September 9, 2004

REMARKS

Applicants thank the Examiner for her September 21, 2004 telephone interview with applicant's attorney. During the interview, the Examiner stated that the September 9, 2004 amendment "amino acids 24-370 of CnA and amino acids 5-168 of CnB" in claims 37-40 introduces a new issue and requires further consideration, and therefore the amendments in the September 9, 2004 Third Supplemental Amendment will not be entered. Applicants also thank the Examiner for her February 8, 2005 telephone interview with applicant's attorney. During the interview, the Examiner stated that that the January 10, 2005 amendment "amino acids 24-240 and 247-370 of CnA and amino acids 5-82 and 84-168 of CnB" in claims 37-40 introduces a new issue and may be new matter, and that the amendments in the January 10, 2005 Amendment and Reply to Final Office Action will not be entered. The Examiner stated, however, that amending step a) of claims 37, 38, 39 and 40 to reflect a CnA (amino acids 17-392)/CnB (amino acids 1-169)/FK506/intact FKBP12 molecular complex as recited on pg. 31, lines 4-13 of the specification as originally filed would overcome the outstanding rejection. Applicants believe that the Amendment submitted herewith overcomes the "new matter" objection in claims 37-40, overcomes the

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outstanding 35 U.S.C. §112, second paragraph rejections,  
and places the claims in condition for allowance.

Applicants have amended claims 37-40 (as they stood prior to the September 9, 2004 and January 10, 2005 Amendments that were not entered) to improve their form. Applicants have amended claims 37-40 to recite "a molecular complex comprising amino acids 17-392 of CnA and amino acids 1-169 of CnB, intact FKBP12, and FK506." Support for this amendment can be found, for example, on page 31, lines 4-13 of the specification as originally filed. These amendments clarify, but do not narrow, the scope of the subject matter of claims 37-40.

Applicants have also amended claims 37-40, 43 and 44, as they did in the September 9, 2004 and January 10, 2005 Amendments, to delete the explicit language directed to the homologue binding pocket and to add a " $\pm$ " to refer to the permitted root mean square deviation from the specific coordinates recited in Figure 1. Support for these amendments can be found, for example, on pg. 10, line 22 to pg. 12, line 25 of the specification as originally filed.

None of these amendments introduces new matter. Applicants request entry of these amendments.

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Applicants have cancelled claims 1-36 and 45-56. Therefore, the rejections to these claims raised in the September 9, 2004 Final Office Action have been overcome. Applicants reserve the right to prosecute any canceled or deleted subject matter in subsequent applications claiming benefit herefrom.

Applicants address in this Reply the remaining rejections pertaining to claims 37-44.

#### Claim Rejections

35 U.S.C. § 112

The Examiner has rejected claims 37-44 under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement. Specifically, the Examiner asserts that producing a crystal of a molecule or molecular complex comprising "amino acids 24-240 and 247-370 of CnA and amino acids 5-82 and 84-168 of CnB" raises a new issue and may be new matter.

As noted in the Remarks *supra*, applicants have amended claims 37-40 to recite "a molecular complex comprising amino acids 17-392 of CnA and amino acids 1-169 of CnB, intact FKBP12, and FK506." Support for these amendments can be found on pg. 31, lines 4-13 of the specification.

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The Examiner has rejected claims 37-40 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as their invention.

Specifically, the Examiner asserts that it is unclear what the antecedent basis of the phrase "said binding pocket" in steps (c) and (e) is intended to be. The Examiner asserts that there is insufficient basis for the phrase "said structure coordinates defining all or part of a binding pocket" in step (d). The Examiner contends that step (c) recites a step of identifying a binding pocket but the claims neither recite defining nor recite identifying structure coordinates for a binding pocket.

Applicants have amended step (c) of claims 37-40 to reflect identifying the structure coordinates of a CnA (CnA/CnB) binding pocket of CnA (CnA/CnB) amino acids. Applicants have also amended claims 37-40 to replace "said binding pocket" with a specified binding pocket, i.e., CnA or CnA/CnB binding pocket. These amendments overcome the lack of antecedent basis in steps (c) and (e) and also provide antecedent basis for the structure coordinates defining said CnA (CnA/CnB) binding pocket in step (d).

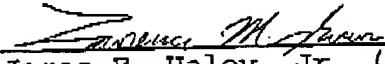
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In view of the above amendments, applicants respectfully request that the Examiner withdraw the 35 U.S.C. § 112 rejections.

CONCLUSION

Applicants request that the Examiner reconsider and enter the amendments and allow the remaining claims. Should the Examiner believe that an interview would be helpful in resolving any remaining issues, she is invited to telephone the undersigned.

Respectfully submitted,

  
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